Enpr-EMA newsletter December 2016

Dear friends and colleagues,

Before the year 2016 draws to a close we want to briefly inform you about the activities of Enpr-EMA throughout the year 2016 and plans for 2017.

Enpr-EMA expanded with the addition of 2 new networks that joined as Enpr-EMA registered

- Category 3:

  - NorPedMed (Norwegian National multispecialty network)

- Category 4:

  - EAPRASnet (European Academy of Paediatrics Research in Ambulatory Settings network)

The TEDDY - European Network of Excellence for Paediatric Clinical Research - was upgraded to category 1 network.

Since official launch of Enpr-EMA in 2011, 50 networks have submitted their self-assessment forms; however, only networks of category 1-4 that updated the forms regularly are visible in the Enpr-EMA Network Database.

At the end of 2016, Enpr-EMA has 39 networks registered in the Enpr-EMA database:

- 21 category 1 networks;
- 4 category 2 networks;
- 13 category 3 networks;
- 1 category 4 network.

Activities of Enpr-EMA Working groups

WG "Dialogue and interaction with Ethics Committees":

Following the successful publication of the table with the requirements regarding consent of children in the various member states, on the Enpr-EMA website, the work has also been published in the scientific journal Archives of Disease in Childhood: Lepola P, et al. Arch Dis Child Published Online First:25 May 2016 doi:10.1136/archdischild-2015-310001.

Contact with the European Network of Research Ethics Committees (EUREC) has been established: the chair of the Enpr-EMA's working group on Ethics was invited to EUREC's annual meeting to present

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
Telephone +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Enpr-EMA. Only one of 34 ethic committees' representatives has heard about Enpr-EMA. This strongly calls for further interaction. A teleconference with the secretary general of EUREC is planned for January 2017 to explore ways of collaboration.

WGs "How to establish communication between Enpr-EMA, networks and industry" and "Sharing good practices within Enpr-EMA and with industry" decided to merge.

Following the successful publication of the final report on the outcomes of the survey with, examples of good practice as well as a list of ideal services that networks can provide was accepted by Applied Clinical Trials journal: Pharmaceutical Industry and Pediatric Clinical Trial Networks in Europe – How Do They Communicate?, the group developed a model how industry can best engage with Enpr-EMA networks and how this could benefit them. The model is currently under final review and will be published on the EMA website next year.

WG "Neonatology":

Enpr-EMA members participated at the Second Annual Scientific Workshop at EMA: Applying Regulatory Science to Neonates on 12-13 September 2016, co-organised by EMA and the Critical Path Institute.

In addition to the working groups in the areas bronchopulmonary dysplasia, neonatal seizure and brain injury, two new workgroups have been launched in November: retinopathy of prematurity (ROP) and hemodynamic adaptation (HA).

An article "The International Neonatal Consortium: collaborating to advance regulatory science for neonates" was published in Pediatric Research (2016) 80, 462–464.

WG on Young Persons Advisory Groups (YPAGs):

The group developed a survey to review currently established YPAGs (within Enpr-EMA and non-Enpr-EMA patient groups). 5 established YPAGs have been identified among Enpr-EMA members; in addition, one Neonatal Parent Forum, the European Forum for Care of the Newborn Infant (EFCNI) responded to the survey.

As next step, the group now plans to develop a database of YPAG's as resource for EMA and Pharma and to develop operational links between the various YPAGs, so that they can work collectively on providing their expertise, attitudes and advice.

Several members of this working group attended the second iCAN (international children's advisory network) summit in June 2016 in Barcelona, where they had the opportunity to meet, discuss and strengthen collaboration with members of Canadian and US youth groups.

Members of the working group also presented the work of YPAGs at the Joint DIA/EFGCP/EMA better medicines for children conference 2016 on optimisation of drug development for the benefit of children (10-11 October 2016).

WG on the Educational Training of Research Staff involved in Paediatric Clinical Trials:

This group developed a questionnaire to gather information on requirements across Europe for the qualification of 'research nurses' and disseminated it to 28 organisations identified for circulation in the UK, Ireland, France, Switzerland, Finland, Norway, Sweden, Denmark, Netherlands, Spain,

Germany, and Italy. While the majority of responders were involved in research in multiple specialties, some were specialised in the field of oncology, haematology and neonatology.

More than 200 responses were received. One third of responding research nurses felt that they would benefit from additional training in the following areas: IT training / clinical trial setup / specialist skills for clinical trials / sample handling / finance / research governance.

The working group now plans to identify additional organisations in countries currently under-represented in dataset obtained and to publish the findings in an appropriate journal with data summary and link to publication through Enpr-EMA website.

New Working groups

One new working group was set up in 2016:

WG clinical trial designs for paediatric antibiotic trials

This working group was triggered by many challenges and difficulties encountered with the conduct of paediatric antibiotic trials. The group plans to review current international regulatory guidance in paediatric clinical trials as well as the literature of conducted and planned paediatric antibiotic clinical trials; to summarise key barriers in design and conduct of such studies and to produce a summary document of key components for the design for paediatric antibiotic clinical trials by first quarter of next year.

We thank all working group members for their enthusiasm and efforts.

Additional Enpr-EMA activities throughout 2016 included:

- 2016 annual workshop of the European network of paediatric research at the European Medicines Agency, followed by the networks and the Coordinating Group meetings (02-03/06/2016). The meeting reports are published on the Enpr-EMA website.
- In May 2016 Enpr-EMA hosted the kick-off meeting of the European Respiratory Society Clinical Research Collaboration (CRC) for “Enhancing participation of asthmatic children in therapeutic trials of new biologics and receptor blockers” at the EMA.
- Several Enpr-EMA members participated at the workshop on paediatric clinical trials organised by Innovative Medicines Initiative (IMI) in preparation of an IMI2 call for at creating a pan-European paediatric clinical trials network. The call will be officially launched on 19 December 2016 https://attendee.gotowebinar.com/register/6129955824720036097 .
- Initiation of regular meetings with the Paediatric Committee (PDCO): in September the INC was presented to PDCO, in November three national networks from UK, Finland and France presented their networks and their activities to the committee. Further meetings will continue throughout 2017 to strengthen the communication and cooperation with the PDCO.
- On 1st December 2016 a webinar on Enpr-EMA was organised to inform about and raise awareness on Enpr-EMA among SMEs and pharma. The presentations and the broadcast will be published on the Enpr-EMA webpage.
- A corporate response from Enpr-EMA and partners was submitted to the European Commission during the public consultation of the document “Ethical Considerations for Clinical Trials on Medicinal products Conducted with Minors”.

In 2017 Enpr- EMA will prepare

- a response to the consultation about the 10 year review of the EU Paediatric Regulation
- a response to the consultation on the ICH E11(R) guideline on clinical investigation of medicinal products in the paediatric population.

The next Enpr-EMA workshop will be on Tuesday, 16 May 2017 at the EMA in London. On the next day there will be a meeting of the network members followed by a meeting of the Coordinating Group.

We thank you all for your support and activities towards Enpr-EMA.

We wish you and your families Merry Christmas, happy holidays and all the best for the New Year. May the year 2017 turn our plans into reality and all our efforts into further achievements to the benefit of paediatric research.

Mark Turner

Chair

Irmgard Eichler

Co-chair